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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,892	11/26/2003	Mathias Alterman	E072.1010.1	5982
7590	03/14/2008		EXAMINER	
WOMBLE CARYLE Post Office Box 7037 Atlanta, GA 30357-0037			STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	
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			03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,892	<b>Applicant(s)</b> ALTERMAN ET AL.
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on December 17, 2007.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,11-16,19-27,32-40 and 43 is/are pending in the application.
  - 4a) Of the above claim(s) 36-40 and 43 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,11-16,19-27 and 32-35 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

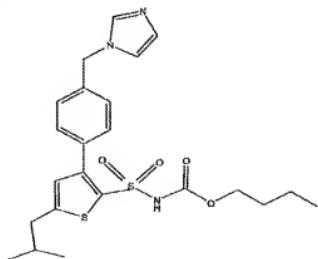
**Claims 1, 11-16, 19-27, 32-40 and 43 are pending in the application.**

***Election/Restrictions***

Applicant's election with traverse of IV (claims 1, 5, 9-27 and 32-35), and the species found on page 34, lines 12-13 (reproduced below) in the reply filed on May 17, 2006 was acknowledged in a previous Office Action.

**Example 1**

**N-Butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butylthiophene-2-sulfonamide**



The requirement was deemed proper and therefore made FINAL in a previous Office Action.

Claims 36-41 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on May 17, 2006.

***Specification***

The filing date of PCT/GB02/02563 on page 1, lines 5-6 of the instant specification, is incorrect.

Rejections and objections made in the previous Office Action that do not appear below have been

overcome. Therefore, arguments pertaining to these rejections and objections will not be addressed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11-16, 19-27 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. {EP 512,675}.

***Determination of the scope and content of the prior art (MPEP 52141.01)***

Applicant claims imidazole compounds. Allen et al. teach imidazole compounds that are structurally similar to the instant claimed compounds and are useful in treating, for example, hypertension (see entire

document; especially Formula I on page 3, the variables definitions on pages 3-13; a subclass of the embodiment starting on page 15; the compositions and methods of use on pages 46-49; and the compounds starting on page 63; particularly a compound such as Compound 51 on page 65).

***Ascertainment of the difference between the prior art and the claims***  
***(MPEP §2141.02)***

The difference between the compounds of Allen et al. and the compounds instantly claimed is that of a hydrogen (as instantly claimed) versus a lower alkyl (as taught by Allen et al., R<sup>1</sup> variable definition on page 3 with variable E defined on page 4 as representing a single bond) on the 2-position of the imidazole ring.

***Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)***

It is well established that the substitution of a hydrogen atom for a lower alkyl on a known compound is

not a patentable modification absent unexpected or unobvious results. In re Lincoln, 53 U.S.P.Q. 40 (C.C.P.A. 1942), In re Druey, 138 USPQ 39 (C.C.P.A. 1963) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e., an angiotension II antagonist).

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught by Allen et al. to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating,

for example, hypertension. In order to establish patentability in adjacent homologs, there must at least be a persuasive comparative showing establishing distinguishing characteristics allegedly showing that claimed compounds are unobvious. Absent a persuasive side by side showing of unexpected, beneficial and superior results of the instant claimed compounds over the compounds taught by Allen et al., the instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

***Response to Arguments***

Applicant's arguments filed December 17, 2007 have been fully considered but they are not persuasive. Applicant argues that: (1) Allen et al. disclose that their compounds are angiotensin II antagonists whereas the compounds of the present invention are useful as angiotensin II agonists and that a different type of utility has been provided by the instant claimed

compounds; and (2) no evidence has been provided to suggest why the skilled person would expect the pharmacological activity to completely change as a result of changing the prior art components to those presently claimed; and that Allen et al. teach away from the instant claimed compounds by having a mandatory substituent at the 2-position of the imidazole ring.

All of Applicant's arguments have been considered but have not been found persuasive. Applicant argues that Allen et al. disclose that their compounds are angiotensin II antagonists whereas the compounds of the present invention are useful as angiotensin II agonists and that a different type of utility has been provided by the instant claimed compounds. In response, a compound and its properties are inseparable. In re Papesch, 137 USPQ 43 (CCPA 1963). The same compound is being administered for the same purpose, i.e., treating hypertension. The utility is not different as

Applicant has alleged. Therefore, Applicant's argument is not persuasive.

Applicant argues that no evidence has been provided to suggest why the skilled person would expect the pharmacological activity to completely change as a result of changing the prior art components to those presently claimed and that Allen et al. teach away from the instant claimed compounds by having a mandatory substituent at the 2-position of the imidazole ring.

In response, Applicant is claiming compounds that are useful in treating the same diseases/disorders that are taught by Allen et al. Therefore, one skilled in the art would be motivated to prepare the compounds of Allen et al., or homologs of Allen et al., to arrive at the instant claimed compounds with the expectation that the prepared compounds would also be useful in treating, for example, hypertension (page 2 of Allen et al.). It is noted that in the instant specification and the originally filed claims in the instant

application that Applicant also discloses and claimed the equivalency of hydrogen and C<sub>1-6</sub> alkyl at the 2-position of an imidazole ring (see the definition of the R<sup>1</sup> variable). Absent a persuasive side by side showing of unexpected, beneficial and superior results of the instant claimed compounds over the compounds taught by Allen et al., the rejection is deemed proper and therefore, the rejection is maintained.

In view of the above rejection of the claims under 35 USC 103 over Allen et al., the elected species of Example 1, found on page 34, lines 12-13 of the instant specification, is not allowable.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 36-41 and 43 drawn to inventions nonelected with traverse in the reply filed on May 17, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-069.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/  
Laura L. Stockton, Ph.D.  
Primary Examiner  
Art Unit 1626, Group 1620  
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March 17, 2008